IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

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| **RUTH SMITH, Individually and as Widow For the Use and Benefit of Herself and the Next of Kin of Richard Smith, Deceased,** | ) | |
| **Plaintiff,** | ) | **Case No. 3:05-0444** |
| | ) | **Judge Aleta A. Trauger** |
| **v.** | ) | **D. Mass. No. 1:05-cv-11515-PBS** |
| **PFIZER INC., *et al.*,** | ) | |
| **Defendants.** | ) | |

**PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' RENEWED MOTION FOR SUMMARY JUDGMENT**

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## PRELIMINARY STATEMENT

On May 13, 2004, Plaintiff Ruth Smith's 79-year old husband, Richard Smith, committed suicide by gunshot, allegedly as a result of ingesting the prescription drug Neurontin, which was sold by Defendants Pfizer Inc. and Warner-Lambert Company LLC. Plaintiff commenced this action in Tennessee state court on May 4, 2005. The case was removed to this Court before being transferred to the multi-district litigation, *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 1629 ("MDL"), in the District of Massachusetts.

On August 14, 2009, Patti B. Saris, the MDL presiding judge, issued two Memoranda and Orders specific to this case. The first Order denied Defendants' motion to exclude the testimony of two of Plaintiff's experts as to whether Neurontin was a specific cause of Mr. Smith's suicide. (*See Smith v. Pfizer Inc.*, D. Mass. No. 1:-05-cv-11515-PBS, Docket No. 9.) The second Order allowed in part Defendants' motion for summary judgment, but reserved for this Court the remaining claims that involved questions of Tennessee law. (Docket No. 10.)

Plaintiff opposes Defendants' pending motion for summary judgment on the grounds that there are genuine issues of material fact as to (1) whether Mr. Smith ingested Neurontin at a time temporally related to his suicide; (2) whether inadequate warnings proximately caused Mr. Smith's suicide; (3) Plaintiff's implied warranty claim; and (4) the fraudulent concealment claim.

## FACTUAL BACKGROUND

Defendants' Memorandum makes numerous allegations concerning Mr. Smith's personal history (that do not include the ingestion of Neurontin), which Defendants claim caused Mr. Smith to commit suicide. None of these statements is relevant and material to resolving the motion for summary judgment in Defendants' favor. To the contrary, Defendants' allegations raise a genuine issue of material fact so as to warrant denial of Defendants' summary judgment

motion. Defendants would have the Court believe that although Mr. Smith was suffering from "excruciating" back pain just prior to his suicide, he refused to take the Neurontin that had been specifically provided to him by his physician and nurse to treat that very back pain.[1]

Defendants concede that on March 9, 2004, Mr. Smith was prescribed Neurontin by his physician, Dr. Edward Mackey, and that Plaintiff purchased the Neurontin that same day (*see* Defs. Statement of Material Facts, MDL Docket No. 1643, ¶¶ 4, 6, 7), and that Mr. Smith was given Neurontin samples in blister packs by Nurse Pamela Krancer. (*See* Defs. Mem., p. 40.) But Defendants insist that there is no evidence Mr. Smith consumed any of this Neurontin.

Regarding the claim that a bottle of Neurontin found in Mr. Smith's bedroom at the time of his suicide was "full" at the time of his death, Defendants fail to mention that Gary Wayne Biggs, the medical/death investigator who investigated the death and collected this bottle, testified at his deposition that he probably did not make a note of how many pills were left in the bottle and could not find any written notation in his notes of how many pills were left in the bottle. (*See* Biggs Dep. 49:14-2--50:1-7, MDL Docket No. 1679, Ex. 24.)

In addition, there is further evidence that Mr. Smith had consumed some of the Neurontin at a time temporally related to his suicide. Plaintiff testified that her husband took his medication in the way that the doctor had prescribed it, and that she knows this to be the case. (*See* Ruth Smith Dep. 143:2-7, MDL Docket No. 1679, Ex. 22.) On April 14, 2004, a month before his suicide, Mr. Smith informed his physical therapist that he was taking Neurontin. (*See* MDL Docket No. 1679, Ex. 31.) On May 8, 2004, five days before his suicide, Mr. Smith informed Wes Carnahan, a pharmacist, that he was taking Neurontin, that the Neurontin made him feel loopy, and that he didn't feel like himself. (*See* Carnahan Dep. 18:21--19-21, 21:6-10,

[1] Plaintiff also alleges in the Amended Complaint that Defendants wrongfully promoted the use of Neurontin for off-label uses, such as for the treatment of back pain, but that argument is not at issue in this motion.

MDL Docket No. 1679, Ex. 26.) And on May 10, 2004, only three days before he committed suicide, Mr. Smith informed his dentist that he was taking Neurontin and that it made him feel weird. (*See* MDL Docket No. 1679, Ex. 1.)

Defendants' Memorandum also fails to discuss facts indicating Mr. Smith would not have been prescribed Neurontin had a suicide warning been included on the label. Defendants' Statement of Material Facts alleges that Dr. Mackey testified that he "probably" read the Neurontin package insert "a long time" before he prescribed Neurontin for Mr. Smith, but that he **typically** did not re-review prescription drug labeling on any kind of regular basis. (*See* Defs.' Statement of Material Facts, MDL Docket No. 1643, ¶ 5 (emphasis added). But Defendants fail to note that Dr. Mackey testified that had he been told that Neurontin was a drug that had these problems, he "probably" would have changed the way he treated Mr. Smith (*see* Mackey Dep. 42:17-25, MDL Docket No. 1679, Ex. 12); and that had Dr. Mackey known of these problems associated with Neurontin, he "[c]ertainly" "would have . . . at least put out some warnings and some safeties and precautions and told them what to be observant about." (*Id.* at 43:1-9.)

Plaintiff's expert Dr. Ronald Maris testified that because Neurontin has a half life of 5 to 7 hours, there would be no appreciable Neurontin left in a person's system within 24 hours after taking the drug. (*See* Defs. Mem. p. 7.) But both of Plaintiff's experts, Dr. Maris and Professor Michael Trimble, have stated that this 5-7 hour half life pertains to the amount of Neurontin in the blood/plasma and not to the amount of Neurontin in the brain. (*See* Plaintiff's Responses to Defendants' Statement of Undisputed Material Facts, Response to Defs.' ¶ 13, MDL Docket No. 1678.) Prof. Trimble also testified that the half-life of gabapentin is extended in elderly persons. (Trimble Dep. 250:4-16, MDL Docket 1679, Ex. 23.) Regarding the length of time it would take for Neurontin to clear an individual's "system" after the last dose, Prof. Trimble testified that

where the individual took multiple doses, like Mr. Smith, the "body becomes saturated with the product. And if you stop taking the drug, you will still get the product emerging from fatty tissue ... so the delay, when you've been taking the drug chronically, is very different." (*Id.* at 258:11-23.) Prof. Trimble further testified that if you have been taking Neurontin for two months, it would take several days at least after your last dose before there is no appreciable Neurontin in your system. (*Id.* at 258:24-259:6.) In addition, in his expert report, Dr. Trimble concluded:

> In the absence of a recognizable psychiatric disorder, the spontaneous and impulsive nature of his suicidal act requires explanation. As outlined in my concurrent report, Gabapentin is associated with changes of brain chemistry which, I find with a reasonable degree of scientific and medical probability, leads to impulsive suicidal acts. It is therefore my opinion that it is more likely than not Gabapentin was a substantial factor in Mr. Smith committing suicide.

(MDL Docket No. 1633-28, p. 13; *see also* Memorandum and Order, MDL Docket No. 2059 (denying Defendants' motion to exclude the specific causation testimony of Prof. Trimble).)

The Court is also referred to other relevant and material facts set forth in Plaintiff's Responses to Defendants' Statement of Material Facts and Further Statement of Material Facts (MDL Docket No. 1678). The assertions in Defendants' Reply (MDL Docket No. 1709) merely raise further genuine issues of material fact in this case that preclude summary judgment.

## SUMMARY JUDGMENT STANDARD OF REVIEW

In numerous opinions, this Court has reiterated its standard of review on a motion for summary judgment. *See, e.g.*, *Christian v. Davidson Transit Org.*, No. 3:08-1025, 2009 U.S. Dist. LEXIS 113704, at *12-15 (M.D. Tenn. Dec. 7, 2009). The standard of review will not be repeated here. Plaintiff does, however, wish to reiterate the Court's statement that "'To prevail, the moving party must meet the burden of proving the absence of a genuine issue of material fact as to an essential element of the opposing party's claim. [Citations omitted.].'" *Id.* at *13.

## I. PLAINTIFF CAN ESTABLISH THE ESSENTIAL ELEMENT OF CAUSATION

### A. There Is Sufficient Evidence That Mr. Smith Ingested Neurontin Temporally Related to His Suicide.

At the outset, it must be noted that the Court of Appeals for the Sixth Circuit has **REVERSED** the case of *Best v. Lowe's Home Centers, Inc.*, No. 04-cv-294, 2008 U.S. Dist. LEXIS 45175 (E.D. Tenn. June 5, 2008), *amended by* 2008 U.S. Dist. LEXIS 56199 (E.D. Tenn. June 24, 2008), Defendants' primary case authority in support of their argument that temporality is insufficient to establish causation (*see* Defs. Mem., pp. 7 n.1, 8). *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171 (6th Cir. 2009); *see also Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 434 (6th Cir. 2009) ("We conclude that when a plaintiff claims that a defendant was negligent in filling a hotel room with a cloud of a poisonous substance, and there is evidentiary support for such claims, expert testimony is not required to show negligence").

In Point I.A.1. of Defendants' Memorandum, Defendants cite the word "speculation", "speculative" or "speculates" no less than nineteen times with respect to whether there is sufficient evidence that Mr. Smith consumed Neurontin at a time temporally related to his suicide, as if such repetition will somehow persuade the Court in this regard. However, Defendants do not cite a single case authority where the defendant drug company has similarly alleged that the plaintiff or decedent refused to take a pharmaceutical drug that had been specifically prescribed to treat his medical condition. Defendants' suggestion that Plaintiff must offer testimony of an eyewitness who saw Mr. Smith popping Neurontin into his mouth during the three days prior to his suicide is also unsupported by any authority.

Neither have Defendants cited any authority that in a products liability wrongful death drug case, the plaintiff must prove that the drug was in the decedent's "system" at the time of death in order to prove proximate cause. Although Defendants question Plaintiff's testimony and

the letter written by Mr. Smith's dentist, both witnesses will be subject to cross-examination at trial. Moreover, that no toxicology tests were conducted after Mr. Smith's suicide by gunshot that could demonstrate the presence of Neurontin in Mr. Smith's system would certainly not be unusual. Defendants also claim that Mr. Smith "failed to take even one pill from a blister pack given to him by his physician's nurse." (Defs.' Mem., p. 10.) But this does not disprove that there were whole blister packs of Neurontin from which Mr. Smith had ingested the Neurontin.

Citing *In re Propulsid Prods. Liab. Litig.*, 261 F. Supp. 2d 603 (E.D. La. 2003), Defendants contend that Plaintiff's allegations that Neurontin can have a prolonged effect on transmitters is speculative. In *Propulsid*, the plaintiff used the drug Propulsid from January, 1996 to May, 1997, and the main basis of the plaintiff's complaint was that Propulsid was defective because it caused her to have a sustained prolonged QT interval, which placed her at risk for sudden death. *Id.* at 604-05. In contrast, here it is not alleged that use of Neurontin by Mr. Smith caused suicidogenic effects that continue long after Mr. Smith allegedly stopped consuming Neurontin. Rather, Plaintiff alleges that even assuming for the sake of argument that Mr. Smith had last consumed Neurontin a mere three days prior to his suicide, the suicidogenic effects of Neurontin would still have been present in his system at the time of his suicide.

Further, as discussed above, both Dr. Maris and Prof. Trimble have stated that the 5-7 hour half-life pertains to the amount of Neurontin in the blood/plasma and not to the amount of Neurontin in the brain. Prof. Trimble also opined that the half-life of Neurontin is extended in elderly individuals, that if you have been taking Neurontin for two months, it would take several days at least after your last dose before there is no appreciable Neurontin in your system, and that Gabapentin is associated with changes of brain chemistry which leads to impulsive suicidal acts.

### B. There Is Sufficient Evidence That Inadequate Warnings Proximately Caused Mr. Smith's Suicide.

Defendants argue that under Tennessee's learned intermediary doctrine, Plaintiff has adduced no admissible evidence that any additional or different warning would have changed any decision made by Mr. Smith's prescriber, Dr. Mackey, or that any different decision by Dr. Mackey would have averted Mr. Smith's suicide.[2] (Defs. Mem. at 13.) In particular, Defendants assert that "'[m]erely raising the possibility that [a physician ]might have acted different is not enough to satisfy Plaintiffs' burden of proof on causation,'" and that "'Plaintiff must provide "affirmative evidence" that "an adequate warning to the prescribing physician would have altered the physician's conduct."'" (*Id.* (citation omitted; emphasis added).)

However, Defendants admitted in their Local Rule 56.1 Statement that "5. Dr. Mackey testified that he 'probably' read the Neurontin package insert 'a long time' before he prescribed Neurontin for Mr. Smith," and that "23. Nurse Krancer testified that she 'doesn't usually read the entire package insert.'" (Defs. Statement, MDL Docket No. 1643, ¶¶ 5, 23 (emphasis added).) More importantly, Dr. Mackey particularly testified that he was not aware of various important information concerning problems with Neurontin, depression and suicide, and that had he been told of these problems with Neurontin, he "[c]ertainly" would have given Mr. Smith specific warnings and told him to be observant about side effects; and Nurse Krancer testified that had Defendants told her that Neurontin was associated with increases in depression and suicide, she would have educated the patients on these potential side effects. (*See* MDL Docket No. 1678, Further Statement, ¶¶ 15-23, re Learned Intermediary.)

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[2] Defendants also note that because the only Neurontin prescription Mr. Smith filled was written by Dr. Mackey, the prescribing decisions of Dr. McCombs and Nurse Krancer are irrelevant. (Defs. Mem. at 13 n.6.) However, the fact that Nurse Krancer did not prescribe Neurontin to Mr. Smith, but gave Neurontin samples to Mr. Smith only means that the learned intermediary doctrine is inapplicable, not that Defendants improperly failed to provide adequate warnings to Nurse Krancer.

Under similar circumstances in *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960 (E.D. Wis. 2009), the court held that a genuine issue of fact existed regarding whether the plaintiff's decedent's physician would have prescribed Paxil if given warnings about risks of increased suicidality in patients. *Id.* at 969.

Thus, there is affirmative evidence that Mr. Smith's medical providers relied on the Neurontin label in providing him the drug. Whether what Mr. Smith's medical providers "probably" or "usually" or "typically" did or did not do is subject to interpretation and raises genuine disputed issues of material fact that may not be resolved by summary judgment.

Defendants also argue that in order to avoid summary judgment, Plaintiff must present evidence "of which there is none here" that if an additional warning had been given, Mr. Smith would nevertheless not have taken the Neurontin. (Defs. Mem., at 14.) However, there is such evidence, as shown by Defendants' earlier strenuous allegations that Plaintiff cannot establish that Mr. Smith took Neurontin or when he took the drug, even without an additional warning.

Defendants have failed to "meet[ ] the burden of proving the absence of a genuine issue of material fact as to an essential element of the opposing party's claim," and "view[ing] the factual evidence and draw[ing] all reasonable inferences in the light most favorable to the non-moving party," *Christian v. Davidson Transit Org.*, 2009 U.S. Dist. LEXIS 113704, at *13, Defendants' summary judgment motion on the issue of proximate cause must be denied.

### C. Summary Judgment Should Be Denied Based on Defendants' New Theory That Suicide Constitutes an Independent Intervening Cause

#### 1. The Court Should Summarily Reject Defendants' Motion for Summary Judgment Based Upon a New Theory

Defendants have now moved for summary judgment based upon an entirely new theory that Defendants could have raised, but inexplicably failed to raise on Defendants' earlier motion

for summary judgment before Judge Saris. Defendants have offered no explanation for this *faux pas*. Defendants cite no recent case indicating that the Tennessee law on this issue was still developing or in conflict at the time the summary judgment motion was submitted to Judge Saris. No prior leave of the Court was requested by Defendants to present this new argument. The only basis for defense counsel's failure to raise the new argument earlier before Judge Saris is counsel's ignorance of Tennessee law.

A party may not advance new theories on a second motion for summary judgment and get a second "bite at the apple." *See Golden Gate Hotel Ass'n v. City & County of San Francisco*, 18 F.3d 1482, 1485 (9th Cir. 1994) ("Defendants' second motion for summary judgment is nakedly an attempt to get another bite of the apple. This court only gives one bite."); *Doherty v. Portland Community College*, No. CV-99-1375-ST, 2000 U.S. Dist. LEXIS 21153, at * 3-7 (D. Or. Nov. 15, 2000) (refusing to allow plaintiff to file a second summary judgment motion, which would "unfairly give to [plaintiff] the proverbial second bite at the apple"); *see also In re Trico Marine Servs., Inc.*, 360 B.R. 53, 61-62 (Bankr. S.D.N.Y. 2007) ("a motion for reargument is not a vehicle for . 'presenting the case under new theories . . . or otherwise taking a "second bite of the apple"'"); *In re Radica Games Ltd. Secs. Limitation*, No. CV-S-94-00653, 1996 U.S. Dist. LEXIS 22833, at *5-8 (D. Nev. Oct. 11, 1996) (reconsideration motion "essentially affords a litigant two bites at the apple").

Similarly, here, there is no reason to give Defendants a second bite at the apple. Defense counsel's ignorance of Tennessee law is no good excuse.

**2. It Was Foreseeable to Defendants That a Patient Such as Mr. Smith Who Was Provided Neurontin Would Be at a High Risk for Suicide**

Defendants assert that the rule in Tennessee is that suicide constitutes an independent intervening cause that breaks the chain of causation, and that there are only three exceptions to

the rule, only one — "where defendant's negligence causes a 'delirium' or 'insanity' that results in self-destructive acts" — of which is even "arguably applicable" here. (*See* Defs. Mem., at pp. 15, 16, 16 n.9. Defendants cite a number of court decisions discussing the inapplicability of the delirium/insanity exception. (Defs. Mem., at pp. 16-18.) Notably, none of the decisions cited by Defendants involve a pharmaceutical company that has been accused of wrongfully selling a prescription drug that allegedly caused a patient who consumed the drug to commit suicide.

Defendants argue that the delirium/insanity clearly does not apply here. But Defendants ignore the opinion of Plaintiff's expert, Prof. Trimble, that Mr. Smith's act of suicide was "spontaneous and impulsive." Whether this impulsive act constitutes temporary delirium or insanity so as to bring it within the exception is a question of fact for the jury.

The doctrine [of independent intervening cause] applies only when the intervening act (1) was sufficient by itself to cause the injury, (2) was not reasonably foreseeable to the negligent actor, and (3) was not a normal response to the negligent actor's conduct." *Rains v. Bend of the River*, 124 S.W.3d 580, 593 (Tenn. Ct. App. 2003). "Foreseeability is the key here because no person is expected to protect against harms from events that he or she cannot reasonably anticipate or foresee or which are so unlikely to occur that the risk, although recognizable, would commonly be disregarded." *Id.* "As a general matter, disputed issues regarding legal cause, intervening cause, and foreseeability must be left to the jury. *Id.* at 596; *see also McClenahan v. Cooley*, 806 S.W.2d 767, 775-76 (Tenn. 1991) ("Just as in the case of proximate causation, the question of superseding intervening cause is a matter peculiarly for the jury because of foreseeability considerations;" "The basic issue is foreseeability, both as to proximate causation and superseding intervening cause, and that is a question of fact rather than of law upon which reasonable minds can and do differ"); *White v. Lawrence*, 975 S.W.2d 525, 529-30 (Tenn. 1998)

("Whether such an act or event constitutes an intervening cause is for the jury to determine unless the uncontroverted facts and inferences to be drawn from the facts make it so clear that all reasonable persons must agree on the proper outcome").

In *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174 (D.N.M. 2008), the plaintiff alleged that defendant Eli Lilly and Company wrongfully sold the prescription drug Prozac, which allegedly caused the plaintiff's decedent to commit suicide. Eli Lilly moved for summary judgment, asserting that under New Mexico law, the decedent's suicide was an independent intervening cause that interrupted the chain of causation and relieved Eli Lilly of liability. The district court held that Eli Lilly had not carried its burden to prove that the suicide was an independent intervening cause, and that there was a genuine issue of material fact regarding whether the suicide was an intervening cause. *Id.* at 1231, 1234.

Similarly, in *Stupak v. Hoffman-La Roche, Inc.*, 287 F. Supp. 2d 968 (E.D. Wis. 2003), the plaintiff alleged that defendant Hoffman-La Roche, Inc. wrongfully sold the prescription drug Accutane, which allegedly caused the plaintiff's decedent to commit suicide as a result of ingesting the drug. Hoffman-La Roche moved to dismiss the complaint, in part on the grounds that under Wisconsin law, suicide constitutes an intervening force which breaks the line of causation from the wrongful act to the death and therefore the wrongful act does not render the defendant civilly liable. The district court held that the factual allegations raised by plaintiff were sufficient to raise a question of fact so as to preclude dismissal. *Id.* at 975.

In *White v. Lawrence*, the plaintiff's decedent committed suicide after taking Antabuse, a prescription medicine that produces a sensitivity to alcohol, which had been prescribed to him by the defendant physician. The Tennessee Supreme Court rejected the defendant's contention that the suicide was an independent intervening cause:

> As the expert testimony in this case demonstrates, the foreseeability or likelihood of a suicide does not necessarily depend upon the mental capacity of the deceased at the time the suicide was committed. The fact that the deceased was not insane or bereft of reason does not necessarily lead to the conclusion that the suicide, which is the purported intervening cause, is unforeseeable. As our cases dealing with proximate or legal causation have indicated, the crucial inquiry is whether the defendant's negligent conduct led to or made it reasonably foreseeable that the deceased would commit suicide. If so, the suicide is not an independent intervening cause breaking the chain of legal causation. Those decisions holding to the contrary are overruled. . . .
>
> The record in this case shows that reasonable minds could conclude that the decedent's act of suicide was a foreseeable consequence of the defendant's negligence in surreptitiously prescribing and administering the Antabuse. The record shows that leading risk factors for suicide include physical illness and depression. The decedent suffered from both. The plaintiff presented medical proof that the decedent's suicide was reasonably foreseeable from a medical standpoint, and that the defendant's conduct was a substantial factor in bringing about the suicide. Both Dr. Pate and Dr. Smith testified that the defendant should have reasonably foreseen that secretly prescribing Antabuse to an alcoholic and depressed patient would cause severe physical problems and could cause the decedent to choose to end his life. The jury could thus find that the suicide was the foreseeable result of the defendant's negligence.

975 S.W.2d at 530.

Although the drug in *White* was prescribed by the defendant physician and was not sold by a pharmaceutical company, the circumstances are very similar to this case at bar. Because the issue of suicide as an independent intervening cause was not raised by Defendants until recently, the record on Defendants' renewed summary judgment motion does not include expert opinion by Plaintiff as to whether Defendants should have reasonably foreseen that providing Neurontin to a depressed patient suffering from back pain could cause the patient to commit suicide. However, in opposing Defendants' motion for summary judgment on general causation, Plaintiff did submit evidence by her general causation expert, Dr. Michael Trimble, who was formerly retained by Defendants, that he had warned of the risk of depression as a result of taking Neurontin, (*see* MDL Docket No. 1200, Exs. 77, 79, 92), as did Cynthia McCormick, a former

FDA employee, in her Clinical Review. (*See* MDL Docket No. 1200, Exs. 15, 35.)

In short, the evidence raises a genuine issue of material fact as to whether it was reasonably foreseeable to Defendants that the ingestion of their prescription drug Neurontin could cause a patient who consumed the drug to commit suicide. Thus, Defendants' motion for summary judgment based upon their new theory that Mr. Smith's suicide was an independent intervening cause should be denied, and the issue should be left for decision by the jury.

## II. THERE IS SUFFICIENT EVIDENCE TO SUPPORT PLAINTIFF'S BREACH OF IMPLIED WARRANTY CLAIM

Defendants contend that Plaintiff failed to provide notice of Defendants' alleged breach of implied warranty within a reasonable time after she discovered or should have discovered any breach, citing *Friedman v. Georgia Showcase Co.*, 27 Tenn. App. 574, 579-80, 183 S.W.2d 9, 11-12 (Tenn. Ct. App. 1944). *Friedman* was a sales contract case where the plaintiff did not provide notice to the defendant of his intent to claim a breach by the defendant until at least two years after the alleged breach, when the pleadings were filed in the case. In contrast, here Mr. Smith committed suicide on May 13, 2004, and this wrongful death lawsuit providing Defendants notice of Plaintiff's breach of implied warranty claim was commenced by Plaintiff Ruth Smith on May 5, 2005, less than a year after her husband's death, and plainly within a reasonable time after Mrs. Smith discovered any breach.

Defendants further contend that in order to bring a claim for implied warranty of fitness under Tennessee law, Plaintiff must prove, *inter alia*, actual reliance by the buyer on the seller's skill and judgment, and that Plaintiff has no evidence of this. (Defs. Mem., p. 19.)

However, there is evidence that Mr. Smith had searched the Internet for information concerning Neurontin, and found information that Neurontin was extremely powerful, with numerous side effects. (MDL Docket No. 1679, Ex. 1.) This is evidence that Mr. Smith relied

on information disseminated by Defendants concerning the safety and effectiveness of Neurontin for treating his pain, and continued to take Neurontin to treat his pain based upon his reliance upon such information. Accordingly, there is evidence that Mr. Smith relied on information disseminated by Defendants concerning the safety and effectiveness of Neurontin for treating his pain, and continued to take Neurontin to treat his pain based upon his reliance upon such information. Moreover, Defendants' Statement of Material Facts admits that Dr. Mackey testified that he "probably" read the Neurontin package insert before he prescribed Neurontin for Mr. Smith. (*See* Defs. Statement of Material Facts, MDL Docket No. 1643, ¶ 5.)

## III. WHETHER BECAUSE OF DEFENDANTS' SUPPRESSION OF DEPRESSION/ SUICIDALITY INFORMATION, OR BECAUSE OF DEFENDANTS' AFFIRMATIVE MISREPRESENTATIONS, PLAINTIFF HAS RAISED TRIABLE ISSUES OF FACT REGARDING DEFENDANTS' FRAUD

It is well established under Tennessee law that concealment or suppression of the truth can constitute fraud. *Patten v. Standard Oil Co. of Louisiana*, 165 Tenn. 438, 443-44, 55 S.W.2d 759, 761 (1933); *see also Gurley v. Hickory Withe Partners, L.P.*, No. W2002-02050-COA-R3-CV, 2003 Tenn. App. LEXIS 674 at *11-13 (Sept. 10, 2003); *Rotello v. Clayton Homes of Delaware, Inc.*, No. 3:03-CV-573, 2006 U.S. Dist. LEXIS 68950 at *5-6 (E.D. Tenn. Sept. 25, 2006); *Anderson v. Warren*, No. W2000-02649-COA-R3-CV, 2001 Tenn. App. LEXIS 958 at *9 (Tenn. Ct. App. Dec. 12, 2001); *cf. B & R Constr. Co. v. Tennessee Investment Props., Inc.*, C.A. No. 191, 1990 Tenn. App. LEXIS 852 at *5-7 (Tenn. Ct. App. Dec. 10, 1990).

In *In re Neurontin Mktg. & Sales Practices Litig.*, 244 F.R.D. 89 (D. Mass. 2007), Judge Saris addressed certification of a class action involving Neurontin where it had been alleged that Defendants suppressed or misrepresented various information related to the safety of Neurontin. *See also In re Lupron Mktg. & Sales Practices Litig.*, MDL No. 1430, 2004 U.S. Dist. LEXIS 18512 at *11 (D. Mass. Sept. 16, 2004), and in *In re Lupron Mktg. & Sales Practices Litig.*, 295

F. Supp. 2d 148, 181 (D. Mass. 2003).

In 1992, the FDA evaluated Neurontin's use for Defendants' sought after epilepsy indication and warned Defendants that patients ingesting Neurontin may suffer worsening depression that may "require intervention or lead to suicide, as it has resulted in some suicide attempts." (MDL Docket No. 1200, Ex. 5, at 0084477.) Nevertheless, Defendants suppressed, concealed and failed to disclose information regarding depression/suicidality to Mr. Smith, and his prescribing physicians, while promoting Neurontin's safety and efficacy for off-label uses.

Defendants failed to provide adequate written depression/suicidality information in Defendants' Neurontin package insert or label, a "Dear Doctor" Letter, or any other written communication to Mr. Smith or his prescribing medical providers.[3] Defendants' acts of suppression are reflected by the absence of any verbal information about depression/suicidality communicated by sales representatives to Mr. Smith's prescribers. Additionally, genuine issues of material fact exist as to whether Defendants' off-label promotion scheme for which they pled guilty, or Defendants' sales details to Mr. Smith's prescribers, influenced, induced and caused Mr. Smith's physicians to prescribe, and Mr. Smith to ingest Neurontin for off-label uses.

As summarized below, Defendants knew about Neurontin's association with depression and suicidality but suppressed information important to Mr. Smith and his medical prescribers:

1. Since 1992, Defendants knew of the FDA's concern about Neurontin's association with depression and suicidality, albeit in the context of Neurontin's on-label indication for epilepsy. The FDA prepared a Combined Medical-Statistical Review of Neurontin and stated "[D]epression, while it may [not be] an infrequent occurrence in the epileptic population, may become worse and require intervention or lead to suicide, as it has resulted in some suicide attempts." (MDL Docket No. 1200-6, Ex. 5, at p. 10; MDL Docket No. 1679, Ex. 5 at 0084477.)

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[3]Defendants suppressed depression/suicidality information in the product label; thus, even in the absence of an actual visit and verbal detail from a sales representative, each physician who prescribed Neurontin did so based upon a label in the physician's possession that did not include depression/suicidality information.

2. In 1995, Defendants' retained consultant — and Plaintiff's expert in this case — Michael Trimble, M.D., provided Defendants a paper, *Psychosis with Gabapentin*, advising that "anticonvulsant drugs influence the mental state, and this can be broken down into adverse and beneficial effects . . . . The main adverse effect of anticonvulsants is the link between anticonvulsant drugs and depression." (MDL Docket No. 1200-109, Ex. 77, at p. 6.)

3. Defendants knew Neurontin's mechanism of action contributes to depression and suicidality, because Neurontin reduces the release of excitatory neurotransmitters (e.g., serotonin) in the brain. (MDL Docket No. 1679, Ex. 9, at pp. 11-14; MDL Docket No. 1679, Ex. 10, at p. 3; MDL Docket No. 1200-6, Ex. 5, at p. 9, ¶ 39.)

4. Defendants' own controlled clinical trial data demonstrated an association with suicidality, as confirmed by the FDA over a decade later. In 2008, an FDA Alert indicated a doubling of the risk for suicidal behavior associated with the use of antiepileptic drugs, including Neurontin. The FDA analyzed 11 drugs, including Neurontin, and specifically stated that the results were generally consistent across all drugs reviewed.

5. Incidences of positive dechallenge/rechallenge psychiatric events have been documented in Defendants' own clinical trials for Neurontin. Since 1990, positive dechallenge/rechallenge reactions of depression were observed by Defendants' own investigators who rendered causal association assessments that the depression was probably related to Neurontin.

6. Since 1990, Defendants' own clinical trials reflected that "Acute Severe Depression" and "Suicidal Ideation" were expected adverse events associated with Neurontin. (*See* MDL Docket No. 1200-98.) Clinical trials demonstrated associated psychiatric adverse drug experiences observed by Defendants' own investigators. (MDL Docket No. 1200-99, Ex. 68, at pp. 13-15.)

7. Defendants' own epilepsy clinical trials performed as part of their New Drug Application for Neurontin reflected safety information on 2,048 people who received Neurontin. In the total exposed population of said New Drug Application, seventy-eight patients reported depression as an adverse event (i.e., 5.3% of the population of patients). (MDL Docket No. 1679, Ex. 5, at 0084447.) There were seven reports of depression as serious adverse events, and nine patients who withdrew from studies because of depression. (MDL Docket No. 1679, Ex. 5, at 0084462.)

8. Defendants' own epilepsy clinical trials, performed as part of their New Drug Application for Neurontin, reflected at least seven cases of "Depression" adverse events that Defendants' own medical investigator considered possibly or probably related to Neurontin; there was observed at least two cases of "Drug Overdose" adverse events considered possibly or probably related to Neurontin by Defendants' investigator. (MDL Docket No. 1679, Ex. 5, at 0084467-0084468.)

9. Defendants' own clinical trials reflected that approximately twice as many Neurontin patients (compared to placebo patients) withdrew as a result of clinically-related psychobiologic events. (MDL Docket No. 1200-6, Ex. 5, at p. 9, ¶ 39.)

10. Defendants possessed post-marketing adverse event reports through 2002, before any potential notoriety bias that Defendants relate to the publicity of this litigation, demonstrating an association of psychiatric adverse events, including depression and suicidality, with Neurontin use. A "safety signal" clearly existed, particularly with off-label uses. (MDL Docket No. 1200-6, Ex. 5, at pp. 175-182, ¶¶ 263-282; pp. 192-195, ¶¶ 313-323.)

Here, Mr. Smith's prescribing medical providers, Dr. Paul McCombs and Dr. Mackey, testified about the material information suppressed by Defendants. Both doctors, in discussing their prescribing practices and risk/benefit analyses for prescribing a drug to Mr. Smith, wanted to know about suicide attempts during clinical trials; depression adverse events during clinical trials, and whether depression and suicidality were side effects. (MDL Docket No. 1679, Ex. 11, at 12:3-12:19, 12:20-14:23, 28:10-29:19; MDL Docket No. 1679, Ex. 12, at 34:14-36:25.) Dr. Mackey acknowledged that had he been informed of depression/suicidality information by Defendants, it would have certainly changed the way he treated Mr. Smith in that he would have warned Mr. Smith. (MDL Docket No. 1679, Ex. 12, at 42:17-43:9, 98:14-99:10.)

Defendants also actively promoted Neurontin to Mr. Smith's prescribing medical providers via direct sales representative detailing to the doctors' offices. (MDL Docket No. 1679, Ex. 13.) Nothing in the record reflects that any of Defendants' sales representatives informed Mr. Smith's prescribing medical providers of Neurontin's association with depression/suicidality. But it is known that the providers were detailed, and Mr. Smith was prescribed Neurontin for pain — an off-label, unapproved use. (MDL Docket No. 1679, Ex. 12, at 28:14-28:19.) In fact, although Defendants acknowledge it was inappropriate to detail physicians other than neurologists and epileptologists (MDL Docket No. 1679, Ex. 14, at 45:8-45:25; *see* MDL Docket No. 1679, Ex. 15, at 009942), Defendants detailed Mr. Smith's neurosurgeon, an orthopedist, and a nurse. In doing so, Defendants, who breached their own internal standards, fraudulently represented to Mr. Smith's prescribing physicians that Neurontin was safe and/or efficacious for indications never approved for use by the FDA (i.e., pain and neuropathic pain).

For example, prior to Mr. Smith's death, Defendants' sales representative actively promoted Neurontin to Mr. Smith's orthopedist, Dr. Mackey, and the doctors in his medical practice on approximately 69 occasions with respect to Neurontin. (MDL Docket No. 1679, Ex. 16.) Dr. Mackey testified that Defendants detailed him about "neuropathic pain", which is an off-label, unapproved use by the FDA. (MDL Docket No. 1679, Ex. 12, at 76:23-77:16.)

Defendants' sales representative actively promoted Neurontin to Mr. Smith's healthcare provider, Nurse Pamela Krancer, on approximately 27 occasions with respect to Neurontin. Defendants' sales representative Ashley Pippin planned to "probe" into where Nurse Krancer was dispensing Neurontin and "get help through her with other surgeons." (MDL Docket No. 1679, Ex. 17.) Defendants' sales representatives clearly acted on this "probe" plan as evidenced by the more than 300 occasions in which Defendants detailed the medical practice and distributed Neurontin samples[4] to the medical practice where both Mr. Smith sought treatment and Nurse Krancer worked. (MDL Docket No. 1679, Ex. 18.)

Defendants' sales representative also detailed Dr. McCombs, a neurosurgeon, on approximately three occasions with respect to Neurontin. (MDL Docket No. 1679, Ex. 19.)

The evidence of Defendants' guilt related to their admitted fraud and off-label promotion scheme, coupled with the documented promotional visits by sales representatives, and testimony from Mr. Smith's prescribing medical providers, demonstrates a genuine issue of material fact as to whether the prescribers were influenced by Defendants' affirmative fraudulent promotion of Neurontin as safe and effective for treatment of pain, depression or anxiety — all off-label uses. *See In re Pharmaceutical Ind. Avg. Wholesale Price Litig.*, 252 F.R.D. 83, 99 (D. Mass. 2008) (where plaintiffs' damages were alleged to be caused by a lengthy course of prohibited conduct

[4] Noteworthy, each distribution of a Neurontin sample to the medical practice also included the Neurontin Label which Defendants admit provided inadequate directions for unapproved uses. This admission is reflected in their 2004 guilty plea for distributing a misbranded drug. (*See* MDL Docket No. 1200-3, Ex. 2.)

that affected a large number of consumers, the showing of reliance need not include direct evidence of reliance by individual consumers of defendants' products").

In *Knipe v. Smithkline Beecham,* 583 F. Supp. 2d. 602 (E.D. Pa. 2008), the federal court addressed a strikingly similar situation. Defendant Smithkline defended claims that its drug Paxil was associated with suicidality and that it misrepresented the safety/efficacy of Paxil. Notwithstanding the lack of a specific affirmative misrepresentation to the prescribing physician, the *Knipe* court denied Smithkline's motion to dismiss the fraud claims where the plaintiff's prescribing physician had been influenced by the medical community and his partners, and his prescribing practices were generally guided by information from many other sources, including medical journals, the PDR, and lectures. *Id.* at 621-22, 623. The *Knipe* court concluded that taken as a whole, such evidence created a genuine issue of material fact as to whether the plaintiff's prescriber was influenced, albeit indirectly, by Smithkline's fraud. *Id.; see also Michael v. Shiley, Inc.,* 46 F.3d 1316 (3d Cir. 1995) (finding sufficient evidence to raise a genuine issue of fact on fraud claim where, despite no direct evidence that prescribers were targeted by defendant, the prescribers had read standard journals to remain current in their field).

Here, Dr. Mackey acknowledged that his understanding of Neurontin's off-label use to treat Dr. Smith's pain was in part based upon his interactions with other doctors in his practice. (MDL Docket No. 1679, Ex. 12, at 27:6-27:13.) Dr. Mackey subscribed to journals and he consulted physicians outside of his practice as well as with his two partners — neither of whom were neurologists or epileptologists — but both had been detailed extensively by Defendants about Neurontin for off-label uses. (MDL Docket No. 1679, Ex. 16; Ex. 12, at 28:20-31:25, 74:1-74:23.) Dr. Mackey acknowledged that he utilized the Physician's Desk Reference, which would have included the Neurontin label, for his risk/benefit analysis before prescribing a drug.

(MDL Docket No. 1279, Ex. 12, at 73:12-73:25.) Dr. Mackey also testified that he had been detailed by Defendants' sales representative regarding Neurontin, who discussed Neurontin usage and provided samples for distribution. (MDL Docket No. 1679, Ex. 12, at 75:7-78:4.)

Further, Plaintiff's marketing expert, Charles King III, Ph.D., explained how Defendants' extensive marketing of Neurontin for off-label uses influenced healthcare providers in the absence of a specific affirmative misrepresentation. (MDL Docket No. 1200, Ex. 20, at p. 44.)

Applying *Knipe* to this case, Plaintiff has raised a triable issue of fact as to Defendants' fraudulent conduct and whether Mr. Smith's prescribing medical providers were influenced, directly or indirectly, by Defendants to prescribe Neurontin to Mr. Smith.

## CONCLUSION

In view of the above, it is respectfully requested that this Court deny Defendants' renewed motion for summary judgment in its entirety.

Dated: December 23, 2009

Respectfully submitted,

**BARRETT & ASSOCIATES, P.A.**

By: **/s/ Charles F. Barrett**
Charles F. Barrett, Esq.
6518 Highway 100, Suite 210
Nashville, TN 37205
Tel.: 615-515-3393
Fax: 615-515-3395

**FINKELSTEIN & PARTNERS, LLP**

By: **/s/ Andrew G. Finkelstein**
Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
1279 Route 300, P.O. Box 1111
Newburgh, NY 12551
Tel.: 800-634-1212
Fax: 845-562-3492

*Attorneys for Plaintiff Ruth Smith*

## CERTIFICATE OF SERVICE

I hereby certify that on this the 23rd day of December, 2009, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Aubrey B. Harwell, Jr., Esq.
W. David Bridgers, Esq.
Gerald D. Neenan, Esq.
Neal & Harwell, PLC
2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219

Prince C. Chambliss, Jr., Esq.
Evans & Petree, PC
1000 Ridgeway Loop Road, Suite 200
Memphis, TN 38120

Mark S. Cheffo, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, NY 10036

**/s/ Charles F. Barrett**
Charles F. Barrett